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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LANDSMAN, ROBERT S	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,917	CADET ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *3,5,11,13 and 15-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6-10,12 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. The Amendment dated 11/22/04 has been entered into the record.

B. Claims 1-32 are pending in the Application. Claims 3, 5, 11, 13 and 15-32 have been withdrawn in view of the fact that they are drawn to a non-elected invention. Therefore, claims 1, 2, 4, 6-10, 12 and 14 are the subject of this Office Action.

C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

A. The objection to the specification has been withdrawn in view of Applicants' amendment to the title.

B. The objection to the specification has been withdrawn in view of Applicants' amendment to page 2 of the specification to include Sequence Identifiers.

C. The objection to the specification has been withdrawn in view of Applicants' removal to the hyperlinks and browser-executable code.

3. Claim Objections

A. The objection of claims 4 and 12 has been withdrawn in view of Applicants' amendment to the claims to remove reference to non-elected SEQ ID NO:3.

4. Claim Rejections - 35 USC § 101

A. The rejection of claims 1, 2, 4, 6-10, 12 and 14 under 35 USC 101, has been withdrawn in view of the fact that, even though a protein comprising SEQ ID NO:1, which is only 81 residues, raises issues under 35 USC 112, first paragraph, full-length mu receptors, as disclosed in the application, do possess utility.

5. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. The rejection of claims 1, 2, 4, 6-10, 12 and 14 under 35 USC 112, first paragraph, has been withdrawn since the mu receptors of the present invention possess utility under 35 USC 101.

B. Claims 1, 2, 4, 6-10, 12 and 14 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action mailed 8/24/04. Applicants argue that the artisan would be able to make and use the presently claimed invention. They also argue that page 28 of the specification teaches the significance of SEQ ID NO:1 and that SEQ ID NO:4 comprises SEQ ID NO:1. Applicants further argue that page 22 of the specification teaches the binding requirements for mu3 receptors.

These arguments have been considered, but are not deemed persuasive. While Applicants have taught that SEQ ID NO:4 is a full-length mu3 opioid receptor, Applicants have not provided sufficient guidance or working examples of mu3 opioid receptors in which the only structural requirement is that it comprise SEQ ID NO1. The protein believed to be encoded by SEQ ID NO:4 (i.e. SEQ ID NO:5) is 314 residues. SEQ ID NO:1 encodes only 26 amino acids. This is approximately 8-9% of the entire full-length protein. Nucleic acid molecules which "hybridize" to the claimed sequences, or those only comprising SEQ ID NO:1 would have one or more nucleic acid substitutions, deletions, insertions and/or additions to that encoding the full-length mu3 receptor. Similarly, the encoded mu3 proteins which only comprise 26 resides of the full-length receptor would comprise one or more amino acid substitutions, deletions, insertions and/or additions. Applicants have not taught which residues are critical for protein function, nor have Applicants provided a function which is specific to mu3 receptors. Claim 1, for example, only recites that the proteins must have "mu3 activity" whereas claim 7, for example, does not even require an activity of the encoded polypeptide. To obviate this part of the rejection, Applicants should add a limitation which specifically defines a mu3 receptor. For example, "wherein the encoded polypeptide has a higher affinity for morphine than for DAMGO."

Furthermore, the breadth of the claims is excessive with regard to claim 1. Applicants, again, have not provided sufficient guidance and working examples of all mu3 opioid receptors from all species, nor is the structure of these receptors predictable in view of the lack of teaching as to what critical residues are required to maintain receptor function. This rejection also extends to polynucleotides which hybridize to those of the present invention.

In summary, the breadth of the claims is excessive with regard to Applicants claiming all nucleic acid molecules which encode mu3 receptors, or those which hybridize to those of the present invention.

Furthermore, there is no guidance as to what residues are critical for maintaining mu3 function, nor is it predictable to the artisan how to make a functional mu3 opioid receptor other than SEQ ID NO:4. Therefore, the Examiner maintains that undue experimentation is required to practice the invention as claimed.

C. The rejection of claim 9 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendment to the claim to recite "isolated."

6. Claim Rejections - 35 USC § 112, first paragraph – written description

B. Claims 1, 2, 4, 6-10, 12 and 14 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 5-6 of the Office Action mailed 8/24/04. Applicants argue that numerous mu1 and mu2 receptors were known at the time of the present invention and that the present invention has found a mu3 receptor which has a fragment of its sequence replaced. Applicants argue that they have adequately described a mu3 receptor, SEQ ID NO:4. Applicants further argue that common techniques can be used to make and identify mu3 receptors.

These arguments have been considered, but are not deemed persuasive. While Applicants may have identified SEQ ID NO:4 as a mu3 receptor, no other species are described, or structurally contemplated, within the instant specification. Therefore, one skilled in the art cannot reasonably visualize or predict critical nucleic acid residues which would structurally characterize the genus of nucleic acids encoding the genus of mu3 proteins claimed, because it is unknown and not described what structurally constitutes any different nucleic acids encoding mu3 receptors, or nucleic acids encoding mu3 receptors from any different species, which are further not described, or any different nucleic acid sequence which "hybridizes" to those SEQ ID NOs of the present invention, or any nucleotide sequence that encompasses unknown and undescribed promotor sequences, introns, allelic variants, or other sequences; thereby not meeting the written description requirement under 35 USC 112, first paragraph.

The fact that mu1 and mu2 receptors were known, or that the artisan may be able to use certain molecular biology techniques does not remedy the fact that the genus of mu3 receptors was not described at the time the present invention was made does not remedy the present situation. To obviate part of the rejection, Applicants should add a limitation which specifically defines a mu3 receptor. For example, "wherein the encoded polypeptide has a higher affinity for morphine than for DAMGO." As stands, the genus of proteins which only are required to comprise, for example, SEQ ID NO:1 is not well described.

7. Claim Rejections - 35 USC § 112, second paragraph

A. Claims 1, 2, 4, 6-10, 12 and 14 remain rejected under 35 USC 112, second paragraph, for the reasons already of record on page 6 of the Office Action mailed 8/24/04. Applicants argue that mu3 receptor activity is characterized by a higher affinity for morphine as compared to DAMGO, or that Ca or NO levels are altered. These arguments have been considered, but are not deemed persuasive. Altering the levels of Ca or NO is not specific to mu3 receptors. It is suggested that the claims be amended to recite a characteristic specific to mu3 receptors, such as "wherein the encoded polypeptide has a higher affinity for morphine than for DAMGO."

B. The rejection of claims 4, 6, 12 and 14 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' arguments that the specification provides specific "moderate" and "high" stringency conditions.

C. Claim 9 is confusing since it recites an "isolated" cell comprising an "isolated" nucleic acid. It is believed that the term "recombinant" cell is more clear. As reads, it is not clear how a nucleic acid molecule can be contained in a cell if the nucleic acid is "isolated." In other words, the nucleic acid would no longer be isolated if present in a cell.

8. Claim Rejections - 35 USC § 102

A. Claims 6 and 7 remain rejected under 35 USC 102 for the reasons already of record on page 7 of the Office Action mailed 8/24/04. Applicants argue that the sequence of Birren is only a "working draft" and is, therefore, not isolated. This argument has been considered, but is not deemed persuasive. Regardless of the final order of the 18 contigs of Birren, the fragment which would hybridize to that of the present invention must have been isolated in order for the nucleic acid (contig) to have been sequenced. There is no requirement in the claims that the nucleic acid molecule have any particular function which would obviate the rejection.

B. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Fimiani et al. (reference AP on the 1449 dated 8/24/04). The claim recites an isolated cell comprising an isolated nucleic acid encoding a mu3 receptor. Given the unclear meaning of this claim, as seen above under 35 USC 112, second paragraph - paragraph C, at least the lung carcinoma cells, which have been isolated (see at least Sections 2.1 and 3.1) contain a nucleic acid encoding a mu3 receptor.

9. Claim Rejections - 35 USC § 103

A. The rejection of claim 14 under 35 USC 102 has been withdrawn in view of Applicants' arguments that Sibson provides no motivation to transfect a cell with the sequence of Birren.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 9 AM-6 PM (eastern); alt F 9 AM-6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman
Primary Examiner
Art Unit 1647

ROBERT LANDSMAN
PATENT EXAMINER